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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,909	04/04/2001	David L. Thompson	P-8999	3722

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MEDTRONIC, INC.
710 MEDTRONIC PARKWAY NE
MS-LC340
MINNEAPOLIS, MN 55432-5604

EXAMINER

OROEZA, FRANCES P

ART UNIT PAPER NUMBER

3762

DATE MAILED: 10/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/825,909

Applicant(s)

THOMPSON ET AL.

Examiner

Frances P. Oropeza

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 April 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because “the external device” is inferentially claimed.

Claim 2 is indefinite because the claim is written as an improper Markush group which should be written as --IMD selected from the group consisting of a pacemaker, a defibrillator, a drug pump and a neurostimulator. The phrase “a combination thereof” is unclear because, as written, this element is read to be a combination of the four previous devices, yet this reading is not supported by the specification. For purposes of this examination, the claim is read as a proper Markush group.

Claim 3 is indefinite because the claim is written as an improper Markush group which should be written as --device includes a sensor selected from the group consisting of a wrist watch sensor, a ring sensor, a patch sensor and a active sock sensor. The phrase “a combination thereof” is unclear because, as written, this element is read to be a combination of the four previous sensors, yet this reading is not supported by the specification. For purposes of this examination, the claim is read as a proper Markrus group.

Claim 5 is indefinite because the claim is written as an improper Markush group which

should be written as --data includes one selected from the group consisting of pressure, oxygen,... and intracardiac impedance.” The phrase “physiological data” is indefinite. For purposes of this examination, the claim is read as a proper Markrus group.

In claim 6, “the wireless communication data sytem” lacks antecedent basis.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Prochazka et al. (US 5562707). Prochezka et al. discloses a wrist worn sensor (14) and controller (15) for providing functional electrical stimulation to an implanted muscle microstimulator (72) (figures 1 and 7 and c 6, ll 45-54). The IMD is a neuro stimulator. The external sensor is a wristwatch sensor, where the wrist position sensor (14) and distal portion of the glove (18A) provide a signal indicating wrist position (c 5, ll 26-35). The medical data is the pressure of muscular stress as the wrist is flexed and extended.

3. Claims 1-2 and 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Feingold (US 4871351). Feingold discloses an implanted medication infusion system (2) linked to the external controller (1) by telemetry. An external sensor (30) provides feedback to the controller (figure 2; c 4, ll 49-58; c 6, ll 43-47). The controller and infusion system have a master / slave

relationship, respectively (c 8, ll 7-11). The IMD is a drug pump. The medical data is heart auscultations, specifically the heart rate.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Feingold (US 4871351) in view of Amano et al. (US 5941837). As discussed in paragraph 3 of this action, Feingold discloses the claimed invention except for the sensor of the external device being a wristwatch sensor and / or a ring sensor.

Amano et al. disclose a health management device and teach that it is known to provide a wrist mounted wristwatch sensor and / or a ring sensor to measure and monitor the heart rate (figure 3B). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implanted medication infusion system as taught by

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Feingold, with the wrist mounted wristwatch sensor and / or a ring sensor as taught by Amano et al. to provide a convenient means to mount the external sensor, so sensed heart rate data can be used to better calibrate the drug treatment provided by the drug infusion system.

As discussed above, the external sensor is a wristwatch sensor.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (703) 605-4355. The examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communication and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO
9/29/02

[Signature]
JEFFREY R. JASTRZAB
PRIMARY EXAMINER

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9/29/02